

### REMARKS

The foregoing amendment is submitted to address the claim objections set forth on pages 2 and 3 of the Office Action. The dependencies of claims 69, 70, 76 and 77 have been amended as requested by the Examiner. The amendment therefore does not raise an issue of new matter and clearly overcomes the objections to the claims. The courtesies extended by the Examiner in this regard are greatly appreciated.

Claims 57, 60-63, 67-69 and 72-77 stand rejected as anticipated by Jordan. The Office Action states that Jordan teaches a moisture barrier film or coating for tablets which utilizes a liquid coating solution comprising polyvinyl alcohol and a variety of other materials including exocellular polysaccharides. It is stated that the liquid solution is sprayed onto pharmaceutical tablets and that this is an effective method of encapsulating the tablets. The rejection is hereby traversed and reconsideration is respectfully requested.

The present invention is directed to a capsule. The capsule comprises two essential materials polyvinyl alcohol and a setting system which includes a hydrocolloid or mixture thereof.

As indicated in the specification pharmaceutical capsules have been manufactured with gelatin because of its exceptional gelling, film forming and surface

active properties. The problem, however, with gelatin is that it is naturally hygroscopic and typically contains from about 10 to 16% by weight of water. This presents a problem with the materials contained within the capsules and especially when the relative humidity within and without the capsule is exceptionally high as described on page 2, lines 6-13. Moisture take up of the fill of a capsule by moisture exchange with or permeation through the capsule shell can adversely effect the properties of the film and therefore has encouraged the art to look for alternatives to the use of gelatin as a capsule forming agent. Polyvinyl alcohol (PVA) has been known as a film forming material which has extremely low water vapor permeability. This low water vapor permeability has made it useful as a coating composition, especially for pharmaceutical formulations like tablets as described in the present specification at page 3, lines 19-23.

However, polyvinyl alcohol does not have exceptionally setting properties which is essential for forming capsules. Indeed, as indicated on page 3, beginning at line 24, PVA has been used in combination with cellulose ethers such as hydroxypropylmethyl cellulose to obtain capsule products. However, to obtain acceptable setting properties of the film forming composition, the hydroxypropylmethyl cellulose content must be very high, even greater than the PVA content. As a consequence, the benefits of PVA are lost because the PVA content must be reduced to such an extent that the low water permeability properties are sacrificed.

It is this problem that the present invention is directed. The purpose of the present invention is to devise a capsule made of polyvinylalcohol which is present as the principal component of the capsule so that low water vapor permeability is a significant property of the capsule. At the same time, the present capsule must have adequate setting properties so that capsules can be formed by conventional dip molding processes.

In this regard, Applicants have determined that the addition of a setting system comprising hydrocolloids such as polysaccharides provide sufficient setting properties yet can be used in an amount wherein the low water vapor permeability properties of the principle component (polyvinylalcohol) remains in tact. It is respectfully submitted that the prior art of record as discussed below does not teach or suggest the presently claimed invention.

Jordan does not disclose a capsule. Instead, the reference discloses a coating for a pharmaceutical tablet and thus is similar to prior art described in the present application at page 3, beginning at line 24. There is no teaching or suggestion of the use of a setting system as required in the present claims because no such setting system is needed. Because Jordan is not involved with the formation of capsules, a setting system which provides excellent setting properties but does not compromise the low water vapor permeability of polyvinyl alcohol is not an issue. Instead, Jordan is merely looking to use polyvinyl alcohol for what it has been known for for many years; namely, a low water permeability agent. Because

Jordan is not forming capsules, Jordan never faced the problem of how to maintain low water permeability yet still maintain setting properties which are required only for the formation of capsules such as by the dip molding method. Therefore, Jordan does not anticipate the claims of the present invention and furthermore, one of ordinary skill in the art would not look to Jordan to solve problems associated with capsule formation.

As further evidence of why Jordan does not anticipate or render obvious, Applicants hereby submit the Declaration of Xiongwei He. In the Declaration, Mr. He reviews experience comparing composition made according to the claimed invention and compositions made according to Jordan. The compositions made according to Jordan do not sit on capsule making mold pins. In contrast, Applicants have discovered that by combining polyvinyl alcohol with a hydrocolloid setting system produces a composition that is capable of sitting on capsule making mold pins. Accordingly, Applicants have shown that a direct comparison between the claimed invention and the art cited by the Examiner, was that the claimed invention is patentably distinct over that art. For this reason, Applicants submit that the rejection of the claims over Jordan should be withdrawn.

Claims 58-59, 63-70, 72-74 and 78-79 stand rejected as being obvious over the combination of Deters (U.S. Patent No. 4,627,850) and Yamamoto (U.S. Patent No. 5,624,223).

Deters is stated to teach hard capsules and soft capsules made by a dip

molding process. The Office Action indicates that Deters teaches a capsule with a first lamina 33 formed of polyvinylalcohol and coated with hydroxypropylmethyl cellulose phthalate. The Office Action admits that Deter fails to teach the setting system required in the present claims. Yamamoto is stated to teach a capsule for pharmaceutical use which comprises a water-soluble cellulose derivative as a film forming polymer and a setting (gelatinizing) agent which can be a polysaccharide hydrocolloid. The rejection is hereby traversed and reconsideration is respectfully requested.

Deters disclose an osmotic capsule which includes two distinct structural components, one comprising a semi-permeable lamina and another comprising a hydrophilic lamina. The semi-permeable lamina includes such polymers as cellulose ethers and the like. The hydrophobic lamina includes polymers from a wide range of materials including polyvinylalcohol as mentioned in column 9, cited by the Examiner. Thus, Deters discloses the type of capsule which is formed from two separate components, one of which is semi-permeable and one which is hydrophilic and the two are maintained as separate components in the capsule system. To the contrary, the present invention is directed to a unitary capsule in which as shown for example in Example 1 on page 9 of the specification, a PVA solution containing PVA and the setting system (a hydrocolloid) are formed into a integral capsule without separate structural components. Thus, in the present invention, the capsule is the combination of PVA and the setting system to form a capsule in which the properties of both the PVA and the setting system are able to achieve the objects of the invention. To the contrary, Deters discloses an entirely different type of capsule

which has separate structural components wherein none of the structural components contain polyvinylalcohol and the setting system of the present invention.

Yamamoto does not cure the deficiencies of the Deters reference. Yamamoto is directed to a hard capsule which employs as the principle component a water-soluble cellulose derivative (e.g. cellulose ether). Because the cellulose ether is the principle component, the capsule suffers from the same problems described in the specification beginning at page 3, line 24. The presence of large amounts of cellulose ethers detracts from the low water vapor permeability properties of the polyvinyl alcohol and thus, Yamamoto alone or in combination with Deters does not lead one of ordinary skill in the art to the claimed invention.

Claims 63-70, 72-78 and 80-81 stand rejected as obvious over Jordan in view of Yamamoto. This ground of rejection cannot stand because the combination of these two references does not lead one of ordinary skill in the art to the claimed invention for the reasons discussed above. Jordan is not directed to a capsule forming system at all but merely provides a PVA barrier as a coating for a tablet. Yamamoto teaches how to make capsules using cellulose ethers as the principle component and therefore does not teach one of ordinary skill in the art how to make a capsule in which PVA is the principle component for its low water vapor permeability properties without detracting from those properties by using a significant amount of a gelling agent such as cellulose ether.

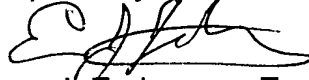
Finally, claim 71 stands rejected as unpatentable over Jordan in view of Frensch. Frensch is stated to teach microcapsules employing an anti-foaming agent. The rejection is hereby traversed and reconsideration is respectfully requested.

The deficiencies of Jordan as a reference against the present application have been discussed above. The addition of an anti-foaming agent to the Jordan method of coating pharmaceutical tablets does not lead one of ordinary skill in the art to the presently claimed invention. To the contrary, the present invention is directed to a capsule in which PVA is the principle component and its low water vapor permeability properties are maintained while employing a setting system (hydrocolloid) which provides ample setting properties without adversely affecting the low water permeability properties of the polyvinylalcohol.

In view of the foregoing, Applicants submit that the present application is in condition for allowance and early passage to issue is therefore deemed proper and is respectfully requested.

It is believed that no fee is due in connection with this matter. However, if any fee is due, it should be charged to Deposit Account No. 23-0455.

Respectfully submitted,



Evan J. Federman, Esquire  
Registration No. 37,060  
Warner Lambert Company

Address All Correspondence to:  
Evan J. Federman, Esquire  
Warner Lambert Company  
201 Tabor Road, 56-2S  
Morris Plains, New Jersey 07950  
(973) 385-5263  
(973) 385-3117 - Facsimile